IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of

John O'Mahony et al. Atty. Ref.: 3659-67

Serial No. 10/601,574 TC/A.U.: 3761

Filed: June 24, 2003 Examiner: DEAK, Leslie R.

For: METHOD AND APPARATUS FOR BLOOD WITHDRAWAL AND INFUSION USING A PRESSURE CONTROLLER

* *

April 7, 2006

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

Applicant hereby appeals to the Board of Patent Appeals and Interferences from the last decision of the Examiner. Petition is made for a one month extension of time to file this Brief.

04/10/2006 HALI11 00000079 10601574
01 FC:2402 250.00 OP

04/10/2006 HALI11 00000080 10601574
01 FC:2251 60.00 OP

TABLE OF CONTENTS

(I) REAL PARTY IN INTEREST

The real party in interest is CHF Solutions Inc., privately held Delaware corporation having a principal office in Brooklyn Park, MN.

(II) RELATED APPEALS AND INTERFERENCES

The appellant, the undersigned, and the assignee are not aware of any related appeals, interferences, or judicial proceedings (past or present), which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

(III) STATUS OF CLAIMS

Claims 82 to 85 are pending and have been rejected. Claims 1 to 36, 40, 44, 58 to 60 and 73 have been cancelled. Claims 37 to 39, 41 to 43, 45 to 57, 61 to 72, and 74 to 81 are withdrawn in view of a PTO restriction requirement. No claims have been allowed.

(IV) STATUS OF AMENDMENTS

An amendment cancelling claims 59 and 60 was filed on April 7, 2006, which is after the Final Rejection of August 25, 2005. Canceling claims 59 and 60 eliminated two of the three rejections in the Final Action.

(V) SUMMARY OF CLAIMED SUBJECT MATTER

The inventions of rejected claims 82 to 85 relate to a leak detector (117) for an extracorporeal blood circuit having blood tubing (104, 105) and a filter (108), and connectable to a blood pump 113 (Qb). [Specification (Spec.) p. 18, ln. 23 to p. 19, ln. 2]. The leak detector and blood circuit are shown schematically in Figure 2 of the application which is reproduced on the next page.

The blood pump periodically reverses the direction of blood flow through the tubing that withdraws and returns blood to the patient through withdrawal and return needles 102, 103. [Spec. p. 9, lns. 17-18; p. 32, ln. 24 to p. 33, ln. 25; p. 46, lns. 8-19; and original claim 4 to 9 and 20, and Abstract]. Reversing the blood flow is used to clear occlusions that can occur in the vein from which blood is being withdrawn. [Spec. p. 9, lns. 18-20]. A vein may collapse due to excessive withdrawal of blood. The collapsed vein occludes the inlet to the withdrawal line needle (102) and prevents blood flow into the blood circuit. When an occlusion is detected, the pressure controller may first slow or stop the blood pump and, if necessary, reverse the blood pump to clear the occlusion. [Spec., p. 32, ln. 24 to p. 33, ln. 4].

A leak detector (117) monitors the blood flow through the tube 104 to detect air bubbles in the blood. [Spec., p. 18, lns. 10-16]. Air in the blood tube indicates a disconnection or leak in the tube. [Spec., p. 25, lns. 24-6 and p. 28, lns. 8-12]. Air bubbles are not to be infused into the veins of the patient. [Spec. p. 9, ln. 22]. When an air bubble is detected, the controller signals an alarm that a disconnection has occurred in the blood circuit and stops the pump. [Spec., p. 28, lns. 8-12]. The leak detector senses air bubbles regardless of the direction of blood flow in the tube. [Spec. p. 28, lns. 8 to

26]. In particular, the disconnect detection algorithms (that are used to sense air in the blood lines) are applied during reverse blood flow. [Spec. p. 32, ln. 28 to p. 33, ln. 5]. Accordingly, leak detection is performed during reverse blood flow and normal flow through the blood circuit.

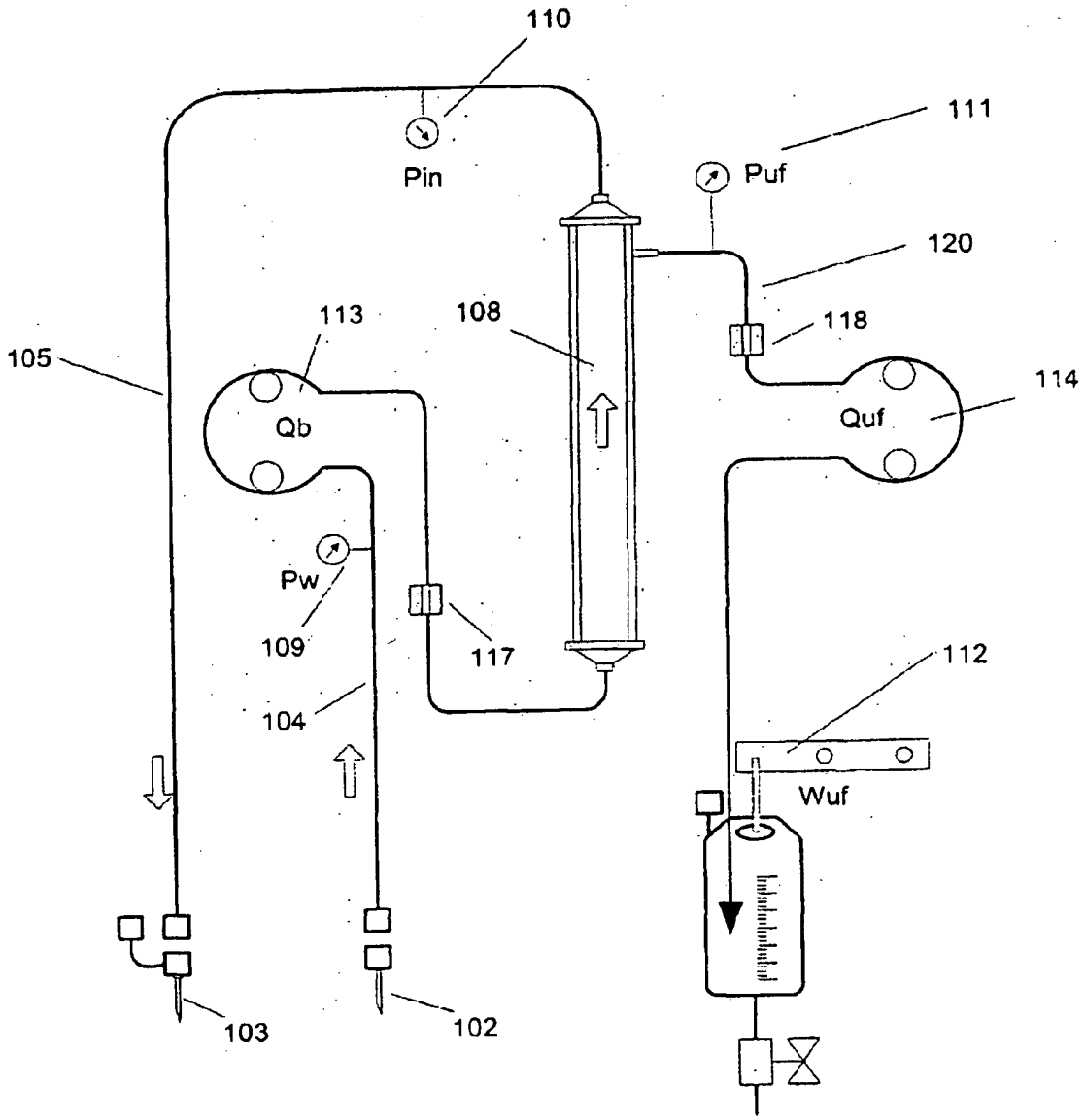

Fig. 2

(VI) GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 82 to 85 are anticipated under 35 U.S.C. §102(b) by Kenley et al (US Patent 5,690,831).

(VII) ARGUMENT

A. Kenley et al Does Not Anticipate or Render Obvious Claims 82 to 85

Claims 82 to 85 are not anticipated or rendered obvious by Kenley et al (US Patent 5,690,831). The rejections of these claims fails because they presume that a blood pump disclosed in Kenley et al generates a negative pressure in a blood return line even though the pump is not coupled to a return line.

Kenley et al do not disclose several features of claims 82 to 85 including:

- a pump actuator having ... a second configuration in which a negative pressure in the return line, whereby a flow through said return line may be reversed ... (Claim 82).
- A pump actuator in the second configuration configured to reverse a flow in both said return line and said draw line. (Claims 83 and 85).
- a pump actuator having a reverse flow operational mode in which the actuator generates a negative pressure in fluid line and a flow through said return line is reversed. (Claim 84).

An anticipatory prior art reference must actually or inherently disclose an invention. The standard for an anticipatory reference is:

> A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference.

SmithKline Beecham Corp. v. Apotex Corp., 74 USPQ2d 1398, 1406 (Fed. Cir. 2005)(citations omitted).

Kenley et al. do not disclose the reversal of blood flow in a return line of an extracorporeal blood circuit. The extracorporeal circuit is shown in Figures 1 and 13 of Kenley et al. The blood withdrawal and return lines connected to the patient are marked as lines 432, 492 in Kenley et al. (col. 26, lns. 1-5 and 63-64). The return line 492 ("venous line") is connected to the drain of a air-separating and pressure monitoring chamber 474 that is filled by the blood pump 458. Kenley et al col. 26, lns. 60-65. There is no pump in the blood line between the drain of the chamber and patient. Kenley et al, Fig. 13.

Kenley et al, at col. 26, lns. 58-60, disclose reversing the blood pump to reduce a fluid level in the chamber 474. The blood pump in Kenley et al is upstream of the chamber 472. The blood pump is controlled to maintain a desired level of blood in the chamber 472. To reduce the level in the chamber, the blood pump is reversed to draw blood out of the chamber. The blood return line in Kenley et al is down stream of the chamber 472. Blood flows from the chamber to the return line. Reversing the blood pump does not create a negative pressure in the return line. At most, reversing the blood pump withdraws blood from the chamber and causes no blood to flow into the return line. Kenley et al do not disclose reversing a blood pump to apply a negative pressure in a blood return line and reverse blood flow in the line. Accordingly, there is no anticipation and the rejection should be withdrawn.

Kenley et al also teaches reversing the blood pump to pump air so as to evacuate fluids (col. 15, lns. 56-61) and to scrub blood products out of the extracorporeal circuit (col. 50, lns. 7-19). In teaching reversal of the blood pump, Kenley et al do not teach reversing the blood flow in a return line connected to a patient.

B. Rejected Claims Were Copied To Provoke Interference With An Issued Patent

The claims on appeal (82 to 85) were substantively copied from US Patent 6,572,576 ('576 Patent) to provoke an interference. The '576 Patent issued from an application filed July 7, 2001. The effective filing date of this application on appeal is November 2, 2000. Accordingly, the invention(s) disclosed in this application were constructively reduced to practice eight months before the invention claimed in the '576 Patent. An interference proceeding is needed to determine the priority of invention.

The claims on appeal were substantively copied from claims 54 and 55 of the '576 Patent. Claims 54 and 55 of the '576 Patent are presented below:

> 54. A leak detector for a sterile contiguous fluid line for infusing a patient, the fluid line including a draw line connectable to at least one patient access and a return line connectable to said at least one patient access, said detector comprising:
> a portion adapted to be interoperable with a pump actuator such that fluid may be conveyed therethrough;
> a filter, or filter connectors to permit connection to a filter, to complete a closed fluid circuit joining said draw and return lines;
> at least a wetted portion of a device configured to generate a negative pressure in said return line, whereby a flow through said return line may be reversed.
>
> 55. A detector line as in claim 54, wherein said device configured to generate a negative pressure is further configured to reverse a flow in both said return line and said draw line.

The pending claims should be allowed for the same reasons that the PTO allowed claims 54 and 55 in the '576 Patent. The allowance of the rejected claims would allow this application to proceed to an interference with the '576 Patent.[1]

CONCLUSION

In conclusion it is believed that the application is in clear condition for allowance; therefore, early reversal of the Final Rejection and passage of the subject application to issue are earnestly solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____
Jeffry H. Nelson
Reg. No. 30,481

JHN:glf
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

[1] Claims 54 and 55 of the '576 Patent are subject to the same infirmities for which cancelled claims 59 and 60 were rejected. In particular, claims 54 and 55 of the '576 Patent and cancelled claims 59 and 60 are directed to a leak detector but do not recite any detection element. Cancelled claims 59 and 60 were rejected for not claiming "essential elements".

(VIII) CLAIMS APPENDIX

Claims 82 to 85 are on appeal and are as follows:

82. A leak detector for a sterile contiguous fluid line for infusing a patient, the fluid line including a draw line connectable to at least one patient access and a return line connectable to said at least one patient access, said detector comprising:

a portion of the fluid line adapted to be interoperable with a pump actuator such that fluid may be conveyed therethrough;

a filter, or filter connectors to permit connection to a filter, to complete a closed fluid circuit joining said draw and return lines;

said pump actuator having a first configuration in which a positive pressure is generated in said return line and a second configuration in which a negative pressure in said return line, whereby a flow through said return line may be reversed when the pump actuator switches from the first configuration to the second configuration, and

a blood leak sensor coupled to said fluid line.

83. A detector line as in claim 82, wherein said pump actuator in the second configuration is further configured to reverse a flow in both said return line and said draw line.

84. A blood flow direction control device for a sterile contiguous fluid line for infusing a patient, the fluid line including a draw line connectable to at least one patient access and a return line connectable to said at least one patient access, said device comprising:

a portion of the fluid line adapted to be interoperable with a pump actuator such that fluid may be conveyed therethrough;

a filter, or filter connectors to permit connection to a filter, to complete a closed fluid circuit joining said draw and return lines;

at least a wetted portion of the portion of the fluid line and the pump actuator having a reverse flow operational mode in which the actuator generates a negative pressure in said fluid line, and a flow through said return line is reversed.

85. A blood flow direction device as in claim 84, wherein reverse a flow is achieved in both said return line and said draw line during the reverse flow operational mode.